IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
	:	**MDL No. 3094**
	:	**24-md-3094**
THIS DOCUMENT RELATES TO:	:	
ALL ACTIONS/ALL CASES	:	

POSITION STATEMENT OF DEFENDANTS NOVO NORDISK AND ELI LILLY

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I. Introduction and Litigation Overview

GLP-1RAs are medicines that have revolutionized the treatment of type 2 diabetes and obesity. Numerous clinical studies have shown that GLP-1RAs reduce the risk of death and adverse cardiovascular events, such as heart attacks and strokes. Ongoing studies suggest they may have additional benefits in addressing kidney disease, liver disease, heart failure, and Alzheimer's. The widespread use of GLP-1RAs is a result of their unprecedented efficacy in the treatment of chronic conditions that impact the daily lives of more than 200 million Americans. As leading researchers stated in the American Heart Association's journal, GLP-1RAs have "changed the landscape" and resulted in a "paradigm shift" in treatment guidelines and clinical practice.[1]

The safety profile of GLP-1RAs has been well-established in hundreds of clinical trials, large-scale observational studies, and nearly two decades of real-world use. The known risks associated with these medicines are reflected in their FDA-approved product labeling—which, collectively, FDA has reviewed more than 40 times—and are discussed in textbooks, treatment guidelines, and journals. The most widely reported risks are the gastrointestinal symptoms alleged in the majority of complaints filed to date (*e.g.*, nausea, vomiting, abdominal pain, etc.).

These facts notwithstanding, Plaintiffs allege that Novo Nordisk ("Novo") and/or Eli Lilly ("Lilly") failed to adequately warn about the risk of gastrointestinal side effects with their GLP-1RA medicines. There are currently 88 cases brought by 117 Plaintiffs (100 against Novo Nordisk, 8 against Lilly, and 9 against both), but according to Plaintiffs' counsel, these cases are a tiny fraction of the tens of thousands of claims they plan to file.

The conditions alleged in the complaints can be grouped into four categories: (1) "gastroparesis" (39 Novo, 6 Lilly, 9 both); (2) ileus/intestinal obstruction (12 Novo, 2 Lilly);

[1] Nikolaus Marx et al., *GLP-1 Receptor Agonists for the Reduction of Atherosclerotic Cardiovascular Risk in Patients with Type 2 Diabetes*, 146 Circulation 1882, 1882 (2022), https://tinyurl.com/2p9u6ces.

(3) some form of gallbladder injury (15 Novo, 0 Lilly); and (4) non-specific gastrointestinal symptoms only (40 Novo, 0 Lilly). Each of these categories involves distinct medical conditions, with different diagnostic criteria, risk factors, clinical data, and FDA regulatory histories; for each, strong scientific and legal defenses exist.

Several threshold issues need to be addressed to allow the Parties to efficiently move forward with the litigation. *First*, the Parties are negotiating a Plaintiff Fact Sheet ("PFS") process that will provide Defendants information about injuries, medical conditions, product identification, symptom onset and timing, and medical/pharmacy records. This is particularly important because (1) the complaints include limited information about the alleged injuries; (2) there has been a substantial spike in compounding[2] and counterfeiting of products that claim to contain semaglutide and tirzepatide; (3) many Plaintiffs who allege "gastroparesis" apparently lack an objective diagnosis (raising a question as to their actual alleged injury, given that specific clinical testing is required to distinguish gastroparesis from other conditions that share similar symptoms); and (4) the gastrointestinal symptoms alleged by Plaintiffs are well-known side effects of these medicines. A robust PFS process will also encourage thorough case evaluation prior to filing.

Second, more information is needed regarding the thousands of additional claims Plaintiffs' counsel have collected so that the Parties and the Court can better understand the scope and focus of the litigation, including the specific injuries, products, and defendants at issue. Without such information, it is difficult to efficiently conduct discovery and to make procedural decisions that navigate and potentially narrow the scope of the litigation (such as whether to move the litigation

[2] Compounding is the process of combining, mixing, or altering ingredients to create a medication for an individual patient. Such products are not branded medicines, and FDA does not approve them or verify their safety, effectiveness, or quality. *See* FDA, *Compounding and the FDA* (2022), https://tinyurl.com/4r6paezx.

forward on separate tracks based on injury type or other factors).

Third, Defendants expect to move to dismiss certain claims, such as design defect, manufacturing defect, and fraud. Although these motions may not dispose of entire cases, they will help shape and streamline the scope of discovery. In addition, Defendants expect to move for early summary judgment on several cross-cutting issues, potentially including causation, adequacy of the warnings, preemption, and statute of limitations. Finally, Defendants anticipate moving to exclude any opinion that a Plaintiff has "gastroparesis" in the absence of required objective diagnostic testing, which would make those claims potentially subject to summary judgment.

Below is a brief background on the disease states, medicines, labeling, and the legal issues that Defendants anticipate will arise in this MDL.

II. Background on the Underlying Disease States

Type 2 Diabetes. Diabetes is a chronic medical condition characterized by elevated blood sugar levels. Approximately 38 million Americans (11.6% of the population) suffer from this disease, which is the eighth leading cause of death in the United States. Other complications of diabetes include cardiovascular disease (heart attack and stroke), kidney disease, nerve damage, blindness, and peripheral vascular disease. Patients with diabetes also are at increased risk for developing a range of gastrointestinal conditions, including gastroparesis, gallbladder disease, and intestinal dysfunction; indeed, diabetes itself is the "most common known cause of" gastroparesis.[3] These same conditions are alleged in most Plaintiffs' complaints.

Obesity & Overweight. Obesity is a chronic medical condition that is one of the leading causes of preventable, premature death. Despite efforts at education and lifestyle intervention, more than 40% of Americans suffer from obesity, and the numbers have continued to rise over

[3] Nat'l Inst. of Diabetes & Digestive & Kidney Diseases, *Gastroparesis* (2018) https://tinyurl.com/ye2mnvzb (cited in McDonald Compl. 16 n.37).

time. Obesity and overweight are associated with a wide range of adverse health effects, including an increased risk of death, high blood pressure, high cholesterol, type 2 diabetes, heart disease, stroke, arthritis, cancer, and chronic pain. Obesity also is associated with gallbladder disease and potentially gastroparesis, the very conditions alleged by Plaintiffs in this litigation.

III. GLP-1RA Medicines at Issue

GLP-1RA medicines are considered first-line treatments for type 2 diabetes and obesity and are prominently recommended in guidelines issued by leading medical organizations such as the American Diabetes Association, the American Heart Association, and the American Gastroenterological Association.[4] GLP-1RAs work by a variety of mechanisms, including by stimulating insulin secretion from the pancreas, slowing gastric emptying, and decreasing appetite or food intake. They are widely recognized for their efficacy and safety, which has been established in hundreds of studies and in millions of patients treated under real-world conditions. Public health economists have estimated that GLP-1RA use will save billions of dollars in healthcare associated with disease-related morbidity and mortality.[5]

A. Novo Nordisk's Semaglutide Medicines

Novo's medicines Ozempic®, Wegovy®, and Rybelsus® all share the same active pharmaceutical ingredient, semaglutide. Each medicine has its own approved clinical uses (or indications), recommended dosing, prescribing information, titration schedules, data, delivery

[4] Am. Diabetes Ass'n Pro. Prac. Comm., *Pharmacologic Approaches to Glycemic Treatment*, 47 Diabetes Care S158, S164 (2024), https://tinyurl.com/yvcnbzfc; Joshua J. Joseph et al., *Comprehensive Management of Cardiovascular Risk Factors for Adults with Type 2 Diabetes*, 145 Circulation e722, e738 (2022), https://tinyurl.com/48dezwec; Eduardo Grunvald et al., *AGA Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity*, 163 Gastroenterology 1198, 1200 (2022), https://tinyurl.com/t2kz2vzk; Marc-André Cornier, *A Review of Current Guidelines for the Treatment of Obesity*, Am. J. Managed Care (Dec. 14, 2022), https://tinyurl.com/37cjbyep.

[5] Dana Goldman et al., *Want Lower Obesity Drug Costs? Medicare Holds the Key*, MedPage Today (2023), https://tinyurl.com/44hztehj.

forms, and product labeling. The products are not interchangeable and should not be used outside of their approved indications.

Ozempic® is a once-weekly injectable formulation of semaglutide that FDA first approved in 2017 for the treatment of type 2 diabetes. In 2020, FDA approved an additional use for reduction of cardiovascular complications. This was based on data from a large-scale trial showing that, compared with placebo, Ozempic® reduced the risk of non-fatal heart attacks in patients with type 2 diabetes and of non-fatal stroke. A recent study also has demonstrated that Ozempic® helps prevent progression of kidney disease in patients with type 2 diabetes.

Wegovy® is a once-weekly injectable formulation of semaglutide approved by FDA in 2021 for chronic weight management. In March 2024, FDA approved an additional use for reduction of major adverse cardiovascular events. This was based on a large clinical trial that found Wegovy® reduced the risk of major adverse cardiovascular events, death, and developing type 2 diabetes. Wegovy® is the first and only FDA-approved anti-obesity medicine that has been shown to reduce the risk of obesity-related complications, such as heart attack, stroke, death, and diabetes. Recent data also suggests that Wegovy® can improve heart failure symptoms in patients with diabetes and obesity.

Rybelsus® is the first and only FDA-approved oral GLP-1 medicine. Rybelsus® has been FDA-approved since 2019 for the treatment of type 2 diabetes and offers patients an alternative to an injection. Results of the Rybelsus® cardiovascular trial are expected later this year.

B. Lilly's Dulaglutide and Tirzepatide Medicines

Trulicity® and Mounjaro® are the two Lilly medicines at issue in this litigation, both of which are FDA-approved to treat type 2 diabetes. Lilly does not promote use of these medicines outside of their approved indications.

Trulicity® is a GLP-1RA medicine approved by FDA in 2014 for treatment of type 2

diabetes. Trulicity® was the first injectable GLP-1RA medication requiring only once-weekly dosing through a unique pre-filled pen delivery device that did not require mixing or needle attachment. In 2020, Trulicity® also became the first medicine approved to reduce the risk of major adverse cardiovascular events in patients with type 2 diabetes. The active ingredient in Trulicity® is dulaglutide. The effects of Trulicity® have been widely studied, with the National Institutes of Health registering at least 100 completed or ongoing clinical research studies involving dulaglutide (including dozens sponsored by Lilly), along with widespread commercial use for nearly a decade.

FDA approved Mounjaro® in 2022, with the active ingredient tirzepatide, as a once-weekly injectable medicine for the treatment of type 2 diabetes. In approving Mounjaro®, FDA described it as "a first-in-class" medication.[6] Unlike Trulicity® and other GLP-1RA medicines, Mounjaro® is a dual-agonist, meaning it activates not only the GLP-1 receptor but also the Glucose-dependent Insulinotropic Polypeptide ("GIP") hormone receptor. GIP is a separate hormone that affects the body's secretion of insulin, which is involved in blood sugar control.

As provided in the Mounjaro® FDA-approved label, in adult patients with type 2 diabetes, "treatment with MOUNJARO produced a statistically significant reduction from baseline in HbA1c [blood sugar level] compared to placebo."[7]

IV. Plaintiffs' Alleged Injuries

A. Gastroparesis

The largest quantity of current claims alleged by Plaintiffs have been characterized as "gastroparesis." Gastroparesis is a relatively rare gastrointestinal condition that is estimated to affect approximately 100,000 persons in the United States.

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[6] *See* FDA, *New Drug Therapy Approvals 2022*, https://tinyurl.com/mr2nnm3t.

[7] In November 2023, FDA approved Zepbound® for chronic weight management in adults with obesity (BMI greater than or equal to 30) or who are overweight (BMI greater than or equal to 27) with certain weight-related conditions. There are no pending cases involving Zepbound®.

Symptoms of gastroparesis—including nausea, vomiting, dyspepsia (indigestion), abdominal fullness, bloating, and reflux—are shared with numerous other conditions. Studies show that approximately **80%** of patients with clinical symptoms of gastroparesis ***do not*** actually have gastroparesis.[8] For this reason, symptoms alone are not sufficient to diagnose gastroparesis.

Instead, objective diagnostic testing is required to confirm that a person in fact has gastroparesis, including evidence of delayed gastric emptying by an appropriate gastric emptying study and radiological testing confirming absence of mechanical obstruction.[9] Only 8 of 54 cases asserting gastroparesis allege confirmatory testing of any kind (8 for Novo; none for Lilly). Absent such testing, these alleged injuries amount to non-specific gastrointestinal symptoms. Defendants expect to challenge whether Plaintiffs have reliable evidence of gastroparesis supported by objective diagnostic testing.

Further confounding Plaintiffs' claims, gastroparesis is a known complication of type 2 diabetes (the condition that Ozempic®, Rybelsus®, Trulicity®, and Mounjaro® are approved to treat) and may be linked to obesity (the condition that Wegovy® is approved to treat). Other known causes of gastroparesis include injury to the vagus nerve, hypothyroidism, and certain autoimmune diseases, nervous system diseases, and viral infections. A substantial percentage of gastroparesis

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[8] David Cangemi et al., *Misdiagnosis of Gastroparesis Is Common*, 21 Clinical Gastroenterology & Hepatology 2670 (2023) (abstract), https://tinyurl.com/bdf9e83b.

[9] Michael Camilleri et al., *ACG Clinical Guideline: Gastroparesis*, 117 Am. J. of Gastroenterology 1197 (2022), https://tinyurl.com/8ccj2unz; Children's Hospital of Philadelphia, *Gastroparesis*, https://tinyurl.com/4ffz48sb; Yale Medicine, *Gastroparesis*, https://tinyurl.com/5825kk2u. The Society of Nuclear Medicine and Molecular Imaging and the American Neurogastroenterology and Motility Society hold out gastric emptying scintigraphy (a nuclear imaging test measuring how long it takes food to empty from the stomach into the small intestine) as the gold standard for the diagnosis of gastroparesis. A. Shin et al., *Diagnostic Assessment of Diabetic Gastroparesis*, 62 *Diabetes* 2667 (2013), https://tinyurl.com/4ajfeyrs; Haider Ghazanfar et al., *Diagnostic Modalities Used in Diagnosing Gastroparesis*, 14 Cureus e30540, at *2 (2022), https://tinyurl.com/3ttfysrk; Yan Wang et al., *Diagnostic Methods for Evaluation of Gastric Motility*, 13 Diagnostics 803, 803, 808 (2023), https://tinyurl.com/ndefnxkc.

cases are idiopathic, meaning that no cause is known. Defendants are not aware of any randomized, controlled study reporting an increased risk of confirmed gastroparesis with semaglutide or tirzepatide. As such, even where Plaintiffs have a reliable diagnosis of gastroparesis, causation will be a key issue.

During the past year, FDA requested information from manufacturers on the effects of GLP-1RAs on aspiration, including data on gastric motility, and the results of FDA's review are still pending.[10] FDA's findings may be relevant to both causation and preemption defenses.

B. Ileus and Intestinal Obstruction

Fourteen Plaintiffs assert "ileus" and/or "intestinal obstruction." While both affect the intestinal tract, they are different conditions with different clinical presentation and features. Ileus refers to a temporary decrease in bowel motility.[11] Symptoms of ileus include bloating, abdominal pain, nausea, vomiting, constipation, loss of appetite, and diarrhea. The most common cause is abdominal surgery. Other causes include some medications (particularly opiates and commonly used anticholinergic medicines such as Benadryl), infections, and kidney failure. Treatment typically involves food restriction, with symptom resolution generally occurring in 1 to 3 days.

Intestinal obstruction refers to a mechanical blockage of the small or large bowel.[12] Symptoms include abdominal pain, bloating, vomiting, constipation, and diarrhea. The most common causes of intestinal obstruction are prior abdominal or pelvic surgery, hernia, certain tumors, diverticulitis, and severe constipation. Defendants are not aware of controlled studies reporting a risk of intestinal obstruction with semaglutide or tirzepatide.

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[10] FDA, *Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS)* (2023), https://tinyurl.com/mr9skym6.
[11] Parswa Ansari, *Ileus*, Merck Manual (2023), https://tinyurl.com/369fewxk.
[12] Parswa Ansari, *Intestinal Obstruction*, Merck Manual (2023), https://tinyurl.com/vpzrr26k.

C. Gallbladder Injury

Fifteen Plaintiffs assert gallbladder injury while taking either Ozempic® or Rybelsus®. (No current cases against Lilly allege gallbladder injuries.) The nature of the gallbladder injuries is unclear, but they likely involve cholelithiasis or cholecystitis. Cholelithiasis refers to gallstones (hardened bile deposits) in the gallbladder. About 15% of the U.S. population has gallstones and, in most cases, they are asymptomatic. Risk factors include female gender, age, overweight, pregnancy, diet, family history, diabetes, liver disease and, importantly, rapid weight loss.

Cholecystitis is inflammation of the gallbladder. Typical symptoms of cholecystitis include abdominal pain, nausea, vomiting, and fever. Gallstones are the most common causes of cholecystitis; other causes include biliary disease, cancer, and infection. Defendants are not aware of any controlled studies reporting a significantly increased risk of cholecystitis with semaglutide.

D. Gastrointestinal Symptoms (Including Severe or Prolonged Symptoms)

Another 40 Plaintiffs allege only non-specific gastrointestinal issues (currently all against Novo, none against Lilly). As discussed below, such gastrointestinal issues (including nausea, vomiting, and diarrhea) are the most common and well-understood side effects associated with GLP-1RA medications—and are described in the FDA-approved product labeling, treatment guidelines, review articles, and textbooks. These gastrointestinal issues are associated with many conditions, including diabetes and obesity, the very conditions for which GLP-1RAs are indicated. These claims may be dismissed on adequacy of warnings, learned intermediary, and other grounds.

V. FDA-Approved Label Warnings[13]

Like all medicines, GLP-1RAs have certain side effects. By far, the most common are gastrointestinal symptoms. These gastrointestinal side effects are reflected in each medicine's

[13] Exhibits A, B, and C include a summary of the Novo labeling, as well as Lilly labels with relevant provisions highlighted.

FDA-approved product labeling (discussed below) and have been recognized in the medical and scientific communities for many years, including in treatment guidelines, review articles, and textbooks relied on by healthcare professionals ("HCPs"). HCPs weigh the risks and benefits of GLP-1RAs (and all medicines) in making treatment decisions for their patients, and these decisions are based on their education, experience, and the specific clinical situation. While Defendants do not promote medicines for off-label uses (*i.e.*, outside the FDA-approved uses), the FDA permits HCPs to use their clinical judgment to prescribe medicines for uses beyond the approved label.

A. Novo's FDA-Approved Label Warnings

Gastrointestinal Symptoms. The FDA-approved product labels for Ozempic®, Wegovy®, and Rybelsus® state in numerous parts that patients may experience gastrointestinal side effects—including nausea, vomiting, diarrhea, abdominal pain, and constipation—and that, in clinical trials, approximately 3% to 8% of patients stopped taking the medicines due to adverse gastrointestinal effects. Ex. A, at 1-2, 5-6, 8-9. The Patient Guide provided with the labeling also notes that "the most common side effects" of these medicines include: "nausea," "stomach (abdominal) pain," "diarrhea," "vomiting," and "constipation," and recommends that patients contact their HCPs if these symptoms persist. *Id.* at 3, 7, 10.

Gallbladder Disease. The Wegovy® label has warned of a risk of Acute Gallbladder Disease since its commercial launch. For Ozempic® and Rybelsus®, the labels always have stated in the Adverse Reactions section that cholelithiasis (gallstones) were reported more frequently in patients treated with these medicines. In 2022, a warning regarding Acute Gallbladder Disease was added to the labeling for Ozempic® and Rybelsus® after FDA completed its review of post-marketing reports of gallbladder-related events in patients taking GLP-1RA medicines.

Ileus/Intestinal Obstruction. In 2022, FDA initiated a review of reports of intestinal obstruction with GLP-1RA medicines. Upon completion of the review, FDA specifically requested

that the term "ileus," *but not intestinal obstruction*, be added to the Adverse Reactions section of the product labeling for all GLP-1RA medicines, including Ozempic®, Wegovy®, and Rybelsus®.

B. Lilly's FDA-Approved Label Warnings

Gastrointestinal Issues. The Trulicity® and Mounjaro® labels have warned since launch that these medicines may be associated with "severe" gastrointestinal reactions—*i.e.*, the very injuries that Plaintiffs assert against Lilly. In the "WARNINGS AND PRECAUTIONS" sections, both labels state: "*Severe Gastrointestinal Disease*: Use may be associated with gastrointestinal adverse reactions, ***sometimes severe***." Ex. B, at 1; Ex. C, at 1 (emphasis added). Both labels also always warned in the same section that these medicines have "not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and [are] therefore not recommended in these patients." Ex. B, at 4; Ex. C, at 4. The Medication Guides further state that Trulicity® and Mounjaro® "**may cause serious side effects, including: . . . severe stomach problems**." Ex. B, at 33; Ex. C, at 21.

In addition, both the Mounjaro® and Trulicity® labels repeatedly warn of vomiting, diarrhea, constipation, dyspepsia (indigestion), and abdominal (stomach) pain, which are listed as the "most common adverse reactions" and the "most common side effects" of Trulicity® and/or Mounjaro®. The "Adverse Reactions" section of the Mounjaro® label, for example, includes the following information: "The most common adverse reactions, reported in >5% of all patients treated with MOUNJARO are: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain." Ex. B, at 1; Ex. C, at 1. Both labels also state that these medicines "slow[]" and "delay[] gastric emptying." Ex. B, at 1, 8, 10, 11, 14; Ex. C, at 1, 7, 10, 11.

Ileus. In 2022 and 2023, respectively, the Trulicity® and Mounjaro® labels added "ileus" as a post-approval reported adverse reaction. Ex. B, at 8; Ex. C, at 7.

Gallbladder. No Plaintiff alleges gallbladder injuries from Trulicity® or Mounjaro®. Both

labels warn: "*Acute Gallbladder Disease:* Has occurred in clinical trials. If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated." Ex. B, at 5; Ex. C, at 4. "Acute Gallbladder Disease" is listed as a potential "serious adverse reaction[]." Ex. B, at 5; Ex. C, at 5.

VI. Preliminary Roadmap

One of the primary efficiencies of the MDL process is the potential resolution of dispositive issues that can narrow or eliminate categories of claims. *See, e.g.*, *In re Asbestos Prods. Liab. Litig. (No. VI)*, 718 F.3d 236, 240-41, 247-49 (3d Cir. 2013). Considering the public health benefits of these medicines and the well-known and labeled risks, it is important to develop a case structure that streamlines and facilitates rigorous evaluation of the legal and scientific viability of Plaintiffs' claims. Defendants propose the following potential sequencing for the identification, categorization, and resolution of key legal, scientific, and factual issues.

A. Step One: Plaintiff Fact Sheets and Docket Metrics

The Parties are negotiating a PFS process that will provide data points on critical dispositive issues, including product identification, causation, statute of limitations, and learned intermediary. By providing information about injuries, medical conditions, product identification, symptom onset and timing, and medical/pharmacy records, the PFS process will permit the Parties and the Court to categorize claims. This will include identifying claim categories that are candidates for early motion practice, targeted discovery, and expert work to ripen cross-cutting summary judgment (and related Rule 702) motions. The PFSs will help balance the asymmetry of case specific information that tilts in favor of Plaintiffs at the beginning of this litigation.

For example, about half of all filed claims in this MDL allege symptoms of gastroparesis. Early identification of which Plaintiffs among the group have gastroparesis diagnoses confirmed by objective testing will be an important case management tool, especially because gastroparesis presents nonspecific symptoms like nausea and vomiting. Claims lacking a confirmed, objective

gastroparesis diagnosis will be candidates for early summary judgment motions to dismiss both the gastroparesis claims (based on no reliable diagnosis) and any claims for other alleged symptom (like vomiting, nausea) because they are well-known and warned-of risks of the medicines.

Further, Plaintiffs' counsel has represented to the Court that they have inventories of, and expect to file, more than 10,000 claims. But they have filed less than 1% of that number, raising questions about the complexion of the ultimate docket. To appropriately focus discovery and identify which legal, scientific, and factual issues will cut across significant numbers of claims, Defendants request that the Court consider making informal inquiries regarding the general complexion of claims that are not yet on file (*e.g.*, types of injuries, confirmatory testing, breakdown by products and defendants, percentage of cases involving hospitalization, etc.) and encourage that Plaintiffs file cases that reflect the array of cases in inventory.

B. Step Two: Early Elimination of Meritless Claims

The PFS process will also provide a tool to advance early resolution of a significant number of cases. *First*, the PFS process may help discourage the filing of meritless claims. *Second*, as is the case with virtually every major personal-injury MDL, some claimants will fail to comply with PFS requirements (whether because their claims lack merit or they choose not to participate in the litigation). *Third*, the sworn responses to PFS questions and required medical, pharmacy, or other records may present candidates for early summary judgment or docket-control show cause orders because, for example, the PFS shows their claims are invalid. For example:

***Product Identification*.** Plaintiffs may not sue Defendants for injuries allegedly caused by counterfeit or compounded products that Defendants did not manufacture, supply ingredients for, or sell. Early production of product identification records and certification of branded product use will allow the Court to dispose of claims lacking product identification at the outset.

***Timing of Injury*.** The timing of Plaintiffs' alleged symptom onset and injury diagnoses

will also be important. Given that many of the injuries alleged in the litigation are associated with the very medical conditions (diabetes and obesity) that are treated by GLP-1RAs, Defendants anticipate that many Plaintiffs may have had those symptoms (in particular gastroparesis and other gastrointestinal disease) before they started using Defendants' medicines—which Lilly's labels warn against. A robust PFS will help identify those claims that are subject to causation, learned intermediary, and other defenses. Date of symptom onset will also be important to assess the relevant statute(s) of limitations, especially since some of these medicines were first commercialized in the United States in 2014 (Trulicity®) and 2017 (Ozempic®).

Other MDL courts have implemented procedures to identify and dismiss claims based primarily on PFS deficiencies. *See, e.g.*, *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 966 F.3d 351, 356-57 (5th Cir. 2020) (affirming dismissal for failure to serve completed PFS); *In re Paraquat Prods. Liab. Litig.*, 2023 WL 10478347, at *2 (S.D. Ill. Mar. 15, 2023) (implementing docket control orders based on concerns about cases "that present implausible or far-fetched theories of liability, and therefore would not have been filed but for the availability of" the MDL).

Further, Defendants expect to move to dismiss certain legal claims (such as manufacturing and design defect, which are pled against Novo but not Lilly) that are extraneous to the litigation or are adequately addressed in the current product label. Facially meritless claims that are allowed to languish would complicate the resolution of the remaining claims. Although these motions may not dispose of entire cases, they will shape and narrow the scope of discovery, thus streamlining discovery and positioning remaining claims for potential resolution on summary judgment.

C. Step Three: Accelerated Cross-Cutting Summary Judgment Motions

The case management structures described above will set the stage for accelerated targeted discovery, expert work, and summary judgment or other dispositive motion practice that will impact and likely dispose of entire categories of claims. For example:

Gastroparesis Claims Lacking Objective Confirmatory Testing. Defendants anticipate a threshold issue will be whether Plaintiffs have a valid gastroparesis diagnosis. Accelerated discovery and expert work intended to address whether Plaintiffs have reliable evidence of gastroparesis may result in the disposition of many claims and impact the scope and merits of others. *See, e.g.*, *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, No. MDL 2848, 2022 WL 17477553, at *2-5 (E.D. Pa. Dec. 6, 2022) (applying earlier summary judgment and Rule 702 orders to dismiss with prejudice 1,189 claims that lacked required confirmatory laboratory testing).

Learned Intermediary/Warnings. Many of the complaints allege gastrointestinal symptoms like nausea, vomiting, constipation, etc. As discussed above, these are well-known, labeled risks of GLP1-RAs and are common knowledge among HCPs to whom the duty to warn runs under the learned intermediary doctrine. "In the MDL context, transferee courts have issued omnibus orders" where, as here, "a drug label [is] adequate as a matter of law" (or because there was no duty to warn of known risks). *See In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 462 F. Supp. 3d 650, 652-53 (E.D. La. 2020) (granting summary judgment on nearly 200 warning claims by chemotherapy patients where label warned of risk of permanent alopecia).

D. Step Four: Notice of Other Potential Early Motions

Defendants also expect to file, at the appropriate time, other motions that may cut across large numbers of cases. These may include:

***General Causation*.** Defendants anticipate bringing motions for summary judgment on at least some alleged injuries because Plaintiffs do not have reliable evidence that the medicines are capable of causing the injury in question. Fed. R. Evid. 702; *see generally In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, — F. Supp. 3d —, 2023 WL 8711617 (S.D.N.Y. Dec. 18, 2023) (excluding under Rule 702 general causation experts' opinions that prenatal exposure to acetaminophen causes autism and/or attention deficit disorder); *In re Zantac (Ranitidine) Prods.*

Liab. Litig., 644 F. Supp. 3d 1075, 1278 (S.D. Fla. 2022) (granting summary judgment on certain cancer claims after excluding plaintiffs' general causation experts under Rule 702).

Preemption. The impact of FDA-approved labeling (and FDA's ongoing review of GLP-1RA medicines in the ordinary course) will be important and may provide opportunities to dismiss certain claims based on preemption. For example, the Court should grant summary judgment where the record shows: (1) Defendants did not have "newly acquired information" supporting a unilateral labeling change or (2) "clear evidence" shows that FDA would have rejected the proposed warning. *See, e.g.*, *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 593 F. Supp. 3d 96, 143-45 (D. N.J. 2022); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007, 1033 (S.D. Cal. 2021). Defendants will promptly notify the Court and the parties if FDA-related events or certain claims provide grounds for early preemption motions.

Statute of Limitations. In light of the well-established association between GLP-1RA medicines and gastrointestinal side effects, some claims may be time-barred based on the date of onset of the alleged symptoms. Statute of limitations defenses are particularly important here because gastrointestinal symptoms typically occur shortly after starting GLP-1RA therapies and are well-known and discoverable.

Case Specific Defenses. Finally, if the litigation reaches the bellwether stage, Defendants expect to have other defenses, including specific causation and warnings causation.

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Respectfully Submitted,

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